PHILIP MORRIS CLINICAL MILESTONES

Philip Morris Project #:	RES 1546/01/04		
MDS Study #:	AA05623		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Pre-Study Proposal Due			
Propose Recruiting Ads	5-May-2004	5-May-2004	
Ad Response/Approval to MDS	7-May-2004	7-May-2004	
Expedited IRB Review of Ads, Text	10-May-2004	10-May-2004	
Expedited IRB Review of Ads, Radio		19-May-2004	
Final Documents to IRB		12-May-2004	
IRB Meeting	18-May-2004	18-May-2004	
Proposed Study Fee to Philip Morris	13-May-2004	13-May-2004	
Pre-Study PA Completed	14-May-2004	14-May-2004	
Recruiting Start Date	15-May-2004	16-May-2004	
Paper Ads to Start	15-May-2004	15-May-2004	
Radio Ads to Start	17-May-2004	19-May-2004	
Screening	4-Jun-2004	4-Jun-2004	
	7-Jun-2004	7-Jun-2004	
Physical Exams	9-Jun-2004	9-Jun-2004	
Call-Outs	15-Jun-2004	15-Jun-2004	
Spec and T/E Complete			
Full Study PA Completed	3-Jun-2004	3-Jun-2004	
Name List Complete	15-Jun-2004	15-Jun-2004	
Check-in	17-Jun-2004	17-Jun-2004	
Baseline	19-Jun-2004	19-Jun-2004	
Check-out	25-Jun-2004	25-Jun-2004	
Return(s)	NA	NA	
QC Issues Final Audit	30-Jun-2004	8-Jul-2004	
Clinical DB Lock	16-Jul-2004	16-Jul-2004	Moved out one week on 8 July 04 (initial CDBL date was 9 July 04)
SM Form to CCRW	23-Jul-2004	15-Jul-2004	
CCSR to SM for review	28-Jul-2004	28-Jul-2004	
SM Respond to CCSR	2-Aug-2004	3-Aug-2004	
CCSR to SM for final review	4-Aug-2004	4-Aug-2004	
SM finalizes CCSR	6-Aug-2004	4-Aug-2004	
CCSR to QA	9-Aug-2004	4-Aug-2004	
QA completes review of CCSR	20-Aug-2004	6-Aug-2004	
QA issues audit of CCSR	23-Aug-2004	6-Aug-2004	
SM send deviations to PM USA	23-Aug-2004		
SM Response to QA audit of CCSR	26-Aug-04		
CCRW gets corrected CCSR to SM	1-Sep-04		
SM verifies CCSR and sends to QA	6-Sep-2004		
CCSR Released as Final	13-Sep-2004		
CCSR signed by PI	15-Sep-2004		
CCSR sent to Archives	16-Sep-2004		

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PHILIP MORRIS DATA MANAGEMENT/STATS MILESTONES

Philip Morris Project #:	RES 1546/01/04		
MDS Study #:	AA05623		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Clinical DB Lock	16-Jul-04	16-Jul-04	
Edit Checks to Begin	20-Jul-04	21-Jul-04	
Edit Checks Completed	30-Jul-04		
Monitoring Visit	None	None	
Initial Creatinine Results Available	14-Jul-04	14-Jul-04	
Amount Excreted Calculated	22-Jul-04	16-Jul-04	
Run Bioplausibility Flowchart #3	22-Jul-04	16-Jul-04	
Creatinine Listing to Philip Morris	22-Jul-04	16-Jul-04	
Philip Morris decision re: re-assays	27-Jul-04	22-Jul-04	
Re-assays completed	3-Aug-04	29-Jul-04	
All Creatinine Results Available	6-Aug-04	29-Jul-04	
Run Bioplausibility Flowchart #3	6-Aug-04	30-Jul-04	
All Creatinine Results to PM for review	6-Aug-04	31-Jul-04	resent on 11 Aug 04
PM decision on analysis exclusion	10-Aug-04		
g for Nicotine, Cot, TransOHCot, NicGluc	20-Aug-04		
ata Listing for CotGluc, TransOHCotGluc	20-Aug-04		
Send Data Listing for NNAL Total	25-Aug-04		
Send Data Listing for NNAL Free	25-Aug-04		Orig. date was 20 Aug - changed per Mohamadi Sarkar
Send Data Listing for 1-OHP	20-Aug-04		
Send Draft Listings of Clinical data to QA	9-Aug-04		
Draft Listings of Clinical data to PM USA	20-Aug-04		
Statistical DB Lock	15-Sep-04		
NOTE: Milestones need to be calculated for the individual data listings requested by Philip Morris. These listings include:			
	Biomarker:	Lock Date:	
	NNAL Total	13-Aug-2004	
	NNAL Free	11-Aug-2004	
Nicotine, Cot, TransOHCot, NicGluc		4-Aug-2004	
	1-OHP	4-Aug-04	
CotGluc, TransOHCotGluc		9-Aug-04	
	Clinical Data	16-Jul-04	

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PHILIP MORRIS REPORTING MILESTONES

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MDS Study #:	AA05623		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Clinical DB Lock	16-Jul-2004	16-Jul-2004	
CCSR Released as Final	13-Sep-2004		
Finalize Reportable Creatinine Results	6-Aug-04	30-Jul-04	
Analytical DB Lock	13-Aug-2004		
Data Listings and Bio Reports Accepted	TBD		
SAP Finalized	1-Sep-2004		First draft to be sent to PM USA 13 Aug 04
Send Draft Tables and Graphs to PM USA	8-Sep-2004		
Statistical DB Lock	15-Sep-2004		
TLG's Finalized	TBD		
Medical Writing Start; Write Protocol Sections, Methods, etc.	TBD		
Write Results Section "A", MW Complete, QC of Protocol, Methods, Etc.	TBD		
Write Results Section "B", QC of Results Section "A", Peer QC of Medical Writing	TBD		
Write Results Section "C", QC of Results Section "B" and Medical Writing	TBD		
Write Results Section "D", QC of Results Section "C"	TBD		
QC of Results Section "D"	TBD		
Send "Working Draft" to PMSM	TBD		
PMSM Review of "Working Draft", MDS Stats Review of Working Draft, Compile and QC Appendices	TBD		
Collaboration Between PMSM and MDSW	TBD		
Write Results, Conclusions and Relevant Synopsis Sections	TBD		
Director, MW and Stats review of "Complete Draft", QC of Results, Conclusions and Synopsis	TBD		

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MDS Study #:	AA05623		
Clinical Site(s) Involved:	LNK		
Milestone:	Scheduled Completion Date:	Actual Completion Date:	Comments:
Address Review Comments	TBD		
QA entire report	TBD		
Address QA comments	TBD		
Send "Complete Draft" to PMSM	TBD		
"Complete Draft" review by Philip Morris, Revisions Sent to MDS	TBD		
Implementation of Revisions**	TBD		
QA entire report	TBD		
Address QA comments	TBD		
"Final Report" Sent to PMSM for Approval	TBD		
PM Review of Final Report and Approval and Communication to MDS	TBD		
Collection of Signatures	TBD		
"Signed Final Report" Issued	TBD		

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